

09/257,739



UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/257,739 02/25/99 HIRSCHMAN

S 5003-36

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ART UNIT 8003 R 9

DATE MAILED:

03/23/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on 12/12/00
- This action is FINAL.

- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire (3) three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 1-4, 7-9 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 1-4, 7-9 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

- All Some* None of the CERTIFIED copies of the priority documents have been received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5 The Examiner acknowledges Applicant's Amendment, Paper No. 8, filed December 12, 2000. In view of Applicant's Amendment, the status of the claims is as follows: Claims 5-6 have been canceled; Claims 1-4 and newly added claims 7-9 are currently pending before the Examiner.

10 The amendment filed December 12, 2000, is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendments at page 4, line 17, and page 9, line 3 attempting to refer to U.S. patent application Serial No. 15 09/344,095 and incorporating the subject matter of said application in its entirety (see Paper No. 8, pages 1-2). Applicant argues that "Product R's physical and chemical properties disclosed in the U.S. patent application Serial No. 09/344,095 are inherent properties resulting from its manufacture so that they are not new matter for the purpose of the present amendment" (see Paper No. 8, 20 page 5, first full paragraph). This is not persuasive. First, U.S. application Serial No. 09/344,095 was filed subsequent to the instant application and applicant cannot rely on subsequently identified properties to enable an earlier filed application. 25 Second, Applicant clearly admits that the procedures of the U.S. application are distinct from those of the instant application (page 5, first full paragraph), albeit Applicant alleges without supportive evidence that the Product R produced by each method is identical. Third, Applicant has incorporated by reference the 30 entirety of the application which includes all matter in the subsequently filed application, not just the physical and chemical properties of Product R.

Applicant is required to cancel the new matter in the response to this Office Action.

Claims 1-4 and newly added claims 7-9 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Applicant argues that the term "Product R" is not indefinite in view of the amendments to the specification. This is not persuasive. As set forth above, the amendments are new matter and are required to be canceled. Thus, the Examiner's position with respect to the term "Product R" set forth in the last Office Action, Paper No. 7, at pages 2-3, remains a valid issue.

Further, claims 1-4 and newly added claims 7-9 remain vague and indefinite with respect to the terminology "amount of said RT-PCR product to determine the reduction of said RT-PCR product" because the claim language still does not indicate to what the RT-PCR is compared against and how the comparison, whatever it may be, relates to the down regulation of the gene. Applicant needs to include appropriate method steps to address these issues in order to clarify the claimed method.

Claims 1-4 and newly added claims 7-9 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Applicant has argued that the amendments to the specification to disclose the physical and

chemical properties of Product R as set forth in U.S. patent application Serial No. 09/344,095 provides sufficient enablement to overcome the rejection (see Paper No. 8, pages 4-5). This is not persuasive.

5 As set forth above, Applicant's amendments to the specification are deemed to be new matter to the instant application are required to be removed from the specification in response to this Office Action. Applicant has not provided any other convincing objective evidence to overcome the rejection with respect to Product R and, therefore, the rejection is deemed proper and is maintained.

10 Applicant further argues that the amendment to the claims with respect to the measurement of the RT-PCR overcome the rejection (see Paper No. 8, paragraph bridging pages 5-6). This is not persuasive. A method claim must necessarily set forth at least the minimum active steps necessary to accomplish the method's intended use. Here, the method continues to lack method steps to guide one skilled in the art as to what property(ies) of the RT-PCR product to compare to what in order to determine a change in RT-PCR product results and how that change, i.e., a reduction in RT-PCR product, for example, relates to the down regulation of gene expression of a HIV co-receptor. Absent these steps, the claim is incomplete, and one skilled in the art would not be able to use the methods of the claimed invention with a reasonable expectation of success and without undue experimentation. Therefore, the specification fails to enable the claimed invention.

15 20 25 30 As set forth in the last Office Action, Applicant should consider amending the claims to include the specific methods of preparation of the particular Product R intended to be encompassed by the claims and to amend the claims to indicate what precise property(ies) of the RT-PCR product are being measured in the

claimed invention and how such measurement(s) correlate with down-regulation of coreceptor gene expression as a means to obviate this rejection.

5 **The claimed invention appears free of the art for the following reasons.** The closest relevant art are Hirschman, U.S. Patent No. 5,807,839 (A), Hirschman, U.S. Patent No. 5,807,840 (B), Bregman, U.S. Patent No. 5,902,786 (C), and most notably, Hirschman et al., *J. Investigative Medicine* 44(6):347-351, August 1996 (R).

10 Each of Hirschman (A), Hirschman (B) and Bregman (C) disclose Product R (Reticulose) which appears to be identical to the Product R of the instant application. Further, each of the references teach different clinical uses for Product R. However, none of the references teach the use of Product R in methods for determining down-regulation of a chemokine receptor.

15 Hirschman et al. (R), the most relevant prior art, discloses methods for studying the mechanisms of action of Product R (Reticulose) using H9 T lymphoma cells and HIV infection (see page 348, "Materials and Methods"). These methods appear analogous to the methods of the claimed invention except that Hirschman et al. does not specifically study the down-regulation of a chemokine receptor which is a coreceptor for HIV. The Examiner notes that in the previous May and June of 1996, just prior to publication of Hirschman et al. (R), several laboratories essentially simultaneously identified CXCR4 and CCR5, chemokine receptors on the surface of T cells, as the putative coreceptors for HIV infection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the methods of Hirschman et al. (R) to study the effects of Product R on chemokine receptor expression. However, it is the Examiner's opinion that, while one of ordinary skill in the art would have been motivated to undertake studies to determine if

Product R had any effect on chemokine receptor expression based on the knowledge that CXCR4 and CCR5 were known coreceptors for HIV, there exists no reasonable expectation of success in such an undertaking. It is the Examiner's opinion that the prior art did not recognize any relationship between Product R and chemokine receptor down-regulation. Therefore, while one of ordinary skill in the art would have been motivated, such an attempt would constitute an "obvious to try" situation with no reasonable expectation of success. On this basis, the Examiner holds Applicant's claimed invention free of the prior art.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also

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be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached at (703) 308-4027.

5 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.



Robert D. Budens
Primary Examiner
Art Unit 1648

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rdb
March 22, 2001